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October 19, 2000

Honorable Donna Shalala  
Secretary of Health and Human Services  
200 Independent Avenue, S.W., Room 615F  
Washington, D.C. 20201

Dear Secretary Shalala:

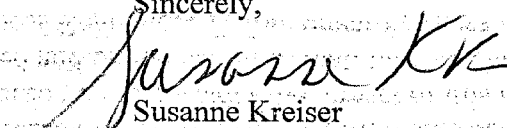
My husband and I are small business owners in Monterey, California, providing hearing health care services to the area's hearing impaired. We have much concern that the Food and Drug Administration (FDA) is reportedly advocating changes to the current hearing aid regulations that would dramatically increase the cost of hearing health care and reduce access to hearing health care providers. We urge you to consider the impact of this proposed hearing aid rule on the nation's hearing-impaired and on the nation's small business hearing health care providers, as required by the Small Business Regulatory Enforcement Fairness Act (SBREFA).

Hearing health care providers like us have been working with the FDA since 1993 to streamline the current FDA hearing aid regulations. Now, just weeks before the election of a new Administration, FDA is rushing to put forth a proposal that could eliminate hearing aid specialists like us from the marketplace. FDA reportedly favors allowing each state to determine the conditions for dispensing hearing aids. This will create inconsistency and confusion and will an intense effort by audiologists to install themselves as the sole gatekeepers to hearing health care without any medical or health policy justification.

As you may have seen, the AARP recently published a *Consumer Guide to Hearing Aids* which found that "almost everyone with a hearing loss hears better with a hearing aid, yet only 20% of those who need a hearing aid have one." Please don't let the FDA erect unwarranted barriers to this safe and effective medical device. We work very hard to assist our clients and strive to bring them the best care and product possible.

Please don't let the FDA publish its proposed hearing aid rule.

Sincerely,

  
Susanne Kreiser  
Franchise Owner

93N 0372

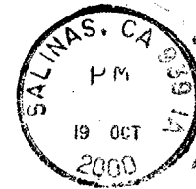
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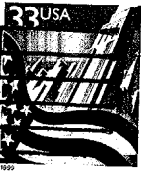


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